

REMARKS

Claims 1 and 43-46 have been amended herein. Claim 8 is cancelled, and claims 3-6, 12-21, and 47-92 are withdrawn without prejudice or disclaimer. Subsequent to the entry of the present amendment, claims 1-2, 7-11, and 22-46 are pending and at issue. The amendments add no new matter, as the claim language is fully supported by the specification and original claims.

I. Rejection under 35 USC § 112, Second Paragraph

Claims 43-46 were rejected under 35 USC § 112 as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The Office Action alleges that the phrase “said condition” in claims 43-46 lack clear antecedent basis. Without acquiescing to the reasoning offered by the Office Action, in order to expedite prosecution towards allowance, Applicants have amended claims 43-46 herein to replace the phrase “said condition” to read “an osteoarthritis disorder,” thereby rendering the rejection moot.

Accordingly, Applicants respectfully request that the rejection under 35 USC § 112, second paragraph be withdrawn.

II. Rejection under 35 USC § 102

Claims 1, 2, 7-11, and 22-44 stand rejected under 35 USC §102 as allegedly anticipated by Lotz et al., WO 02/078445 (hereinafter, “Lotz”). As claim 8 is cancelled herein, the rejection as it applies to this claim is moot. Applicants respectfully traverse the rejection as it applies to the remaining claims on the following grounds.

To anticipate a claim, the single prior art reference must disclose “all of the elements and limitations of each claim, and there must be no difference between the reference disclosure and the claimed invention. *Scripps Clinic & Research Found. v. Genentech, Inc.*, 18 USPQ2d 1001 (Fed. Cir. 1991); *see also In re Spada*, 15 USPQ2d 1655 (Fed. Cir. 1990); *Connell v. Sears Roebuck & Co.*, 220 USPQ 193, 198 (Fed. Cir. 1983); MPEP §2131. Moreover, the reference must be enabling. *Akzo N.V. v. U.S. Int'l Trade Commission*, 1 USPQ2d 1241, 1245 (Fed. Cir. 1986) *cert. denied*, 482 U.S. 909 (1987).

The Office Action alleges, in pertinent part, that Lotz “discloses a method of treating cartilage degradation in a patient that involve administering to a patient a composition containing a therapeutically effective amount of N-acetylglucosamine which exhibits anti-inflammatory and chondroprotective properties by interfering with cytokine-inducible gene expression in chondrocytes, wherein the N-acetylglucosamine may be used alone or in combination with at least one other anti-inflammatory drug or a hexoaminidase inhibitor.” (Office Action, pages 3-4.)

As currently amended, independent claim 1 recites in its entirety “[a] method of treating an osteoarthritis related disorder in a mammal comprising administering a compound to said mammal, wherein said compound further comprises a therapeutically effective amount of an aminosugar derivative, wherein said aminosugar derivative is a derivative of glucosamine or a pharmaceutically acceptable salt thereof, and wherein the derivative of glucosamine is not N-acetyl glucosamine.” Lotz does not recite a method of treating an osteoarthritis disorder in a mammal by administering a therapeutically effective amount of a derivative of glucosamine or a pharmaceutically acceptable salt thereof, and wherein the derivative of glucosamine is not N-acetyl glucosamine. Because Lotz does not anticipate each and every element of the subject claims, nor does the reference enable the claims, the standard for anticipation has not been met.

Accordingly, Applicants respectfully request that the rejection under 35 U.S.C. 102(b) be withdrawn.

III. Rejection under 35 USC § 103

Claims 1, 2, 7-11 and 22-46 stand rejected under 35 U.S.C. §103 as allegedly obvious over Lotz in view of Menard et al., US 6,38,451 (hereinafter, “Menard”). This rejection is respectfully traversed on the following grounds. As claim 8 is cancelled herein, the rejection as it applies to this claim is moot. Applicants respectfully traverse the rejection as it applies to the remaining claims on the following grounds.

The U.S. Supreme Court decision in the *KSR International v. Teleflex Inc.* (82 USPQ2d 1385), modified the standard for establishing a *prima facie* case of obviousness. Under the KSR rule, three basic criteria are considered. First, some suggestion or motivation to modify a reference or to combine the teachings of multiple references still has to be shown. Second, the combination has to suggest a reasonable expectation of success. Third, the prior art reference or

combination has to teach or suggest all of the recited claim limitations. Factors such as the general state of the art and common sense may be considered when determining the feasibility of modifying and/or combining references.

As currently amended, independent claim 1 recites “[a] method of treating an osteoarthritis related disorder in a mammal comprising administering a compound to said mammal, wherein said compound further comprises a therapeutically effective amount of an aminosugar derivative, wherein said aminosugar derivative is a derivative of glucosamine or a pharmaceutically acceptable salt thereof, and wherein the derivative of glucosamine is not N-acetyl glucosamine.”

Pending claims are not obvious over Lotz

The Office Action alleges, in pertinent part, that Lotz “discloses a method of treating cartilage degradation in a patient that involve administering to a patient a composition containing a therapeutically effective amount of N-acetylglucosamine which exhibits anti-inflammatory and chondroprotective properties by interfering with cytokine-inducible gene expression in chondrocytes, wherein the N-acetylglucosamine may be used alone or in combination with at least one other anti-inflammatory drug or a hexoaminidase inhibitor.” (Office Action, page 5.) As discussed above, a review of Lotz reveals that the cited reference does not recite a method of treating an osteoarthritis related disorder in a mammal comprising administering a compound to said mammal, wherein said compound further comprises a therapeutically effective amount of an aminosugar derivative, wherein said aminosugar derivative is a derivative of glucosamine or a pharmaceutically acceptable salt thereof, and wherein the derivative of glucosamine is not N-acetyl glucosamine, as currently claimed.

Therefore, one of ordinary skill in the art would not practice Applicants’ invention using the teachings of the cited reference, since the impression left to the skilled artisan is that the ultimate result of practicing the claimed method would not have the property sought by the Applicants. *In re Caldwell*, 319 F.2d 254, 256, 138 USPQ 543 (CCPA 1963).

Therefore, there is no suggestion or motivation to modify Lotz to arrive at the invention as claimed with a reasonable expectation of success. Furthermore, the cited reference does not teach or suggest all of the recited claim limitations. As such, no *prima facie* case for obviousness exists.

Pending claims are not obvious over Lotz in view of Menard

The Office Action then provides Menard, alleging, in pertinent part, that “[i]t would have been obvious to one of ordinary skill in the art at the time the invention was made to include in the method of administering N-acetylglucosamine to treat cartilage degradation in view of the recognition in the art, as evidenced by Menard et al patent, that glucosamine compounds are known component of compositions that have been used as therapeutic agents for preventing cartilage degradation.” (Office Action, page 6.)

A review of Menard reveals that the cited reference does not recite administration of an aminosugar derivative of glucosamine or a pharmaceutically acceptable salt thereof, and wherein the derivative of glucosamine is not N-acetyl glucosamine, as a method of treating an osteoarthritis related disorder, as currently claimed. In fact, Menard does not recite or disclose any aminosugar derivative of glucosamine that is not N-acetyl glucosamine

Therefore, one of ordinary skill in the art would not practice Applicants’ invention using the teachings of the cited references, either alone or in combination, since the impression left to the skilled artisan is that the ultimate result of practicing the claimed method would not have the property sought by the Applicants. *In re Caldwell*, 319 F.2d 254, 256, 138 USPQ 543 (CCPA 1963).

Therefore, there is no suggestion or motivation to modify Lotz and/or Menard to arrive at the invention as claimed with a reasonable expectation of success. Furthermore, the cited references do not teach or suggest all of the recited claim limitations, either alone or in combination. As such, no *prima facie* case for obviousness exists. Accordingly, Applicants respectfully request that the rejection under 35 U.S.C. §103 be withdrawn.

CONCLUSION

In view of the amendments and above remarks, it is submitted that the claims are in condition for allowance, and a notice to that effect is respectfully requested. The Examiner is invited to contact Applicant's undersigned representative if there are any questions relating to this application.

It is believed that no fees are due with the filing of this response. However, if any fees are due, the Commissioner is authorized to charge any fees, or make any credits, to Deposit Account No. 502235 referencing the above-identified attorney docket number.

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Respectfully submitted,

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